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**510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® Screw Hole Plugs**

K965056

Submission Information

**Name and Address of the Sponsor
of the 510(k) Submission:**

Osteonics Corporation
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Contact Person:

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Date of Summary Preparation:

December 17, 1996

Device Identification

Proprietary Name:

Osteonics® Screw Hole Plugs

Common Name:

Prosthesis, hip, cement restrictor

Classification Name and Reference:

Surgical mesh
21 CFR §878.3300

Predicate Device Identification

The Osteonics® Screw Hole Plugs are substantially equivalent to the following competitive and/or Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Osteonics® Omnifit® UHMWPE Acetabular Shell Cement Spacer System,
- Osteonics® Acetabular Screw Hole Plugs,
- Osteonics® Universal Cement Plug

Device Description

The Osteonics® Screw Hole Plugs are small circular plugs which are manufactured from low density polyethylene and which are intended to occlude all acetabular dome screw holes not occupied by bone screws. The Osteonics® Screw Hole Plugs will be factory-assembled to every

acetabular dome screw hole in the acetabular shell. Intraoperatively, the surgeon will remove the plugs from whichever screw holes will be filled with a bone screw.

The Osteonics® Screw Hole Plugs, by occluding the shell screw holes, will help prevent intrusion of bone cement into the shell and potential migration of debris through open screw holes into the acetabulum.

Intended Use:

The Osteonics® Screw Hole Plugs are intended to occlude the unused dome screw holes of any Osteonics acetabular shell component. The Osteonics® Screw Hole Plugs will be used either with or without bone cement depending upon the labeled indications of the associated acetabular shell component. The Osteonics® Screw Hole Plugs do not carry their own indications and contraindications, but-- as accessories to acetabular shell components-- would be subject to all of the indications and contraindications of the associated acetabular shells.

Statement of Technological Comparison:

The substantial equivalence of the subject devices to the predicate devices, in terms of design, materials, and intended use are discussed below.

Design:

The subject Osteonics® Screw Hole Plugs and the predicate Osteonics® Acetabular Screw Hole Plugs are both circular disks intended to occlude unused screw holes. The subject devices are pre-assembled to their shells at Osteonics, and may be removed by the surgeon intraoperatively. The predicate devices were not pre-assembled, but instead were assembled to their shells intraoperatively.

Materials

The subject devices are made from low density polyethylene. The predicate cement plug is made from the same low density polyethylene as the subject device. The subject devices have been designed so that they contact neither the acetabular insert nor the acetabular host bone. Because the subject devices are non-load bearing, low density polyethylene is an appropriate material for this application.

Intended Use:

Both the subject Osteonics® Screw Hole Plugs and the predicate Osteonics® Acetabular Screw Hole Plugs are intended to occlude unused screw holes, thus preventing potential intrusion of bone cement and potential emigration of debris through the shell screw holes into the acetabulum. Both the subject and predicate devices are intended for cemented or cementless applications, depending upon the intended use of the associated acetabular shell.

Performance Data:

Laboratory testing has been performed to evaluate the ability of the screw hole plugs to perform as intended under simulated physiological loading.